Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12477

0 - FRONT

HFS-635

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

COMPLAINT / INJURY REPORT

1. COMPLAINT NUMBER: 1-7-1738 12477

2. DATE OF COMPLAINT (Month / Day / Year): 6/4/97

3. FORM OF COMPLAINT
a.
(1) [x] TELEPHONE
(2) [ ] LETTER
(3) [ ] VISIT

4. SOURCE OF COMPLAINT
a.
(1) [xx] CONSUMER (3) [ ] TRADE SOURCE
(2) [ ] GOVERNMENT (4) [ ] OTHER
[ ] L [ ] S [ ] F (Indicate in Remarks)

5. COMPLAINANT IDENTIFICATION
a. NAME AND ADDRESS (Include ZIP Code): [redacted]
b. AREA CODE AND TELEPHONE NUMBER
HOME ([redacted]
WORK ([redacted]

6. COMPLAINT OR INJURY
a. DESCRIPTION OF COMPLAINT / INJURY
Ms. [redacted] said her son 15 years old, took Your Gas a Dietary Supplement, which is used to boost energy. She said this was his first time taking the drug, but within 15 minutes after he took the drug, he had a reaction. He was taking to the Doctor, about time they arrived to the Doctor his symptoms were gone. She said she gave him Benedryl prior to taking him to the Doctor.

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?
(1) [ ] NO (2) [xx] YES
(If "Yes" Explain in Remarks)

7. INJURY OR ILLNESS RESULTED
(1) [ ] NO
(2) [xx] YES *
*(If "yes" complete items a through d)

a. EIB (HFC - 161) NOTIFIED
(1) [x] YES
(2) [ ] NO
DATE: faxed 6/23/97

b. TYPE SYMPTOMS — ONSET (HR.)
(1) [ ] VOMITING
(2) [ ] NAUSEA
(3) [ ] DIARRHEA
(4) [ ] FEVER
(5) [xx] SKIN/EYE IRR eyes rolled back,
(6) [xx] HEADACHE head pulled back, lost control of neck muscle
(7) [xx] OTHER muscles in neck stood out chest stucked out, arms & hands lost muscle control

c. ATTENDING HEALTH PROFESSIONAL?
(1) [xx] NO (2) [ ] YES
(If "Yes" give name, address, and phone number)

d. HOSPITALIZATION REQUIRED?
(1) [ ] NO (2) [ ] YES
(If "Yes" give name, address, phone number and dates)

RECEIVED
JUL 10 1997

8. PRODUCT AND LABELING
a. BRAND NAME: Up Your Gas
b. PRODUCT NAME: Dietary Supplement
c. SIZE AND PACKAGE TYPE: 30 tablets plastic btl
d. NAME AND LOCATION OF STORE WHERE PURCHASED: [redacted] (do not remember exact location)
e. PACKAGE CODE / SERIAL NUMBER / ETC.: #3435A5 (Bar Code:2693210090)
EXP. / USE BY DATE:
f. DATE PURCHASED: approx 1 year ago
g. PRODUCT USED (If "Yes" enter date) (1) [ ] NO (2) [x] YES Date:
h. AMT. REMAINING: yes

9. MANUFACTURER / DISTRIBUTOR OF PRODUCT
a. HOME DISTRICT: Newark
b. C.F. NO.: 2244049
c. NAME AND LOCATION OF FIRM (Include ZIP Code):
Garden State Nutritional
One Hundred Lehigh Drive
Fairfield, New Jersey 070702
d IMPORT PRODUCT
(1) [xx] NO
(2) [ ] YES

10. EVALUATION AND DISPOSITION
a. PROBLEM KEY WORD
(1) CODE: RX
(2) DESCRIPTION: REACTION
b. EVALUATION
(1) [ ] NOT AN FDA OBLIGATION
(2) [ ] OBLIGATION, NO VIOLATION
(3) [xx] FDA ACTION INDICATED
(4) [ ] INSUFFICIENT INFORMATION
UNABLE TO EVALUATE

b. DISPOSITION
(1) [ ] IMMEDIATE FOLLOW-UP
(2) [ ] F / U NEXT EI
(3) [ ] CLOSED WITHOUT FURTHER INVESTIGATION
(4) [ ] REFERRED TO OTHER FEDERAL AGENCY (Closes File)
(5) [ ] REFERRED TO STATE / LOCAL AGENCY (Closes File)
(6) [xx] REFERRED TO OTHER FDA T DISTRICT
(7) [ ] REFERRED TO OCI

11. PRODUCT CODE: 54YEB99

12. INFORMATION COPIES TO:
[ ] HFM-660 [ ] HFZ-343
[ ] HFD-730 [x] HFC-161
[ ] HFV-210 [x] HFS-635
[ ] OTHER Myla Chapman (Fraud Rep)

13. REMARKS: Ms. [redacted] also added her husband used this product a year ago with no problem.

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14. NAME AND TITLE OF DISPOSITION OFFICIAL: Pauline Mills/CCC

15. DATE: 6/20/97

FORM FDA 2516 (5/94)

*U.S. GPO 1994-301-026/00410